UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

September 23, 2004

MEMORANDUM

Subject: Acute Toxicity Review for EPA Reg. No.: 63761-I/ Sterilex Ultra

DP Barcode: D307223

To: Marshall Swindell, PM 33 / Tony Kish
Regulatory Management Branch
Antimicrobials Division (7510C)

From: Ian Blackwell, Biologist
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Through: Karen Hicks, Team Leader
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510C)

9/23/04

Michele E. Wingfield, Chief
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Antimicrobials Division (7510C)

Applicant: The Sterilex Corp.

FORMULATION FROM LABEL:

Active Ingredient(s):	% by wt.
N-Alkyl dimethylethylbenzyl ammonium chloride	3.00
n-Alkyl dimethylbenzyl ammonium chloride	3.00
Hydrogen Peroxide	6.30
Other Ingredient(s):	87.70
Total:	100%

I BACKGROUND: Lewis & Harrison, acting for The Sterilex Corporation, have submitted a rebuttal to a 11/6/2003 AD letter discussing science and labeling issues of their submission to the Agency last year. This 6/4/2004 letter addresses efficacy, labeling (font size) and other issues. The portion of the letter pertaining to this review is "acute toxicity data request", beginning on page 2 of 11.

The submission includes a CSF dated 6/4/2004. It appears that this CSF was composed or revised several months *after* AD's response memo of 11/6/2003.

CTT/PSB notes that the consultants, Lewis & Harrison, state that a portion of this letter is in response to a previous CTT/PSB acute toxicity review of 63761-I. However, no copy of that review could be located in CTT files, by the PM Team, or, in OPPIN. It appears that the consultants may have been thinking of a review of another Sterilex product.

The rebuttal states:

1 CTT/PSB was wrong in stating that the cited product (63761-3) contained three times the level of hydrogen peroxide (HO).

Reg. No. 63761-3: [redacted] = 6.3% HO
File Symbol 63761-I: [redacted] 6.3% HO

2 CTT/PSB was wrong in stating that the registration product and the cited product contain different quats.

Both 63761-3 and 63761-I contain [redacted] as the source of quats (the active ingredients).

3 CTT/PSB was wrong in stating that the cited product has a surfactant whereas the proposed product does not.

Neither product contains a surfactant.

4 No information is available to identify the composition and compare Ultra Kleen Solution 2 (required second component) with that of the proposed product.

This information is included in MRID Number 445927-01.

5 The waiver of the dermal sensitization study is denied because the product contains different levels of quats and hydrogen peroxide, different quats, one has surfactants and information on Solution 2 is unavailable. Please refer to #1 - 4 above.

6 CTT/PSB was wrong to deny the request for the waiver of the acute inhalation study because it was "not substantiated".

The request for a waiver is based on the results of the particle size study developed for the concentrated version of the proposed product, Dental Unit Water Line Powder (EPA File Symbol 63761-L). The toxicity category II results from the inhalation testing would be applied to the label statement for Sterilex Ultra Disinfectant Cleaner Solution 1. (CTT/PSB actually considers this a request to cite the acute inhalation toxicity study conducted on 63761-L, not a waiver request.)

II RECOMMENDATIONS: PSB findings are:

1 CTT/PSB agrees that:

A According to the CSFs of 63671-I and 63671-3, both products contain approximately 6.62% hydrogen peroxide.
B According to the CSFs of 63671-I and 63671-3, both products contain the same quats.
C Neither 63761-I nor 63761-3 contains surfactants.

2 In regard to the request for the waiver of the acute inhalation toxicity study, CTT/PSB/AD finds the formulation of 63761-L to be too dissimilar to 63761-I [redacted] to cite its acute inhalation toxicity study. Also, as this was not an actual waiver request (they didn't state the product is too viscous, not volatile, etc.), the waiver is denied. The registrants may submit an actual waiver request if they desire.

3 CTT/PSB finds that 63761-I and 63761-3 are not substantially similar. However, CTT/PSB will allow the registrant to bridge the primary eye and skin irritation studies from 63761-3. We do not feel confident that the other four studies are bridgeable. The difference is in the ingredient [redacted] (in 63761-3), which contains some ingredients that concern CTT/PSB due to their reported toxicity and irritation.

4 CTT/PSB/AD asks that the registrant submit acute oral toxicity, acute dermal toxicity, acute inhalation toxicity and dermal sensitization studies to support this product.

5 CTT/PSB recommends that the PM Team have the registrant test Solution 2 of this product also.

The acute toxicity profile for File Symbol 63761-I is currently:

Study	MRID Number	Toxicity Category	Acceptability
acute oral toxicity			Data Gap
acute dermal toxicity			Data Gap
acute inhalation toxicity			Data Gap
primary eye irritation	445927-04	I	Cited
primary skin irritation	445927-05	I	Cited
dermal sensitization			Data Gap

III LABELING:

No precautionary labeling can be recommended at this time.